

Amendments to the Specification

Please replace paragraph 2 found on page 4 of the specification with the following amended paragraph:

According to the US Food and Drug Administration's (FDA's) Biopharmaceutics Classification System (BCS), drug products are classified into four groups based on the ability of a given drug substance to permeate biological membranes and its aqueous solubility: Class I drugs are highly permeable, highly soluble; Class II drugs are highly permeable, poorly soluble; Class III drugs are poorly permeable, highly soluble; and Class IV drugs are poorly permeable, poorly soluble (The Biopharmaceutics classification system (BCS) guidance, Center for Drug Evaluation and Research, US Food and Drug Administration (FDA), 2001, www.fda.gov/cder). A drug substance is considered "highly soluble" when the highest dose strength is soluble in 250 ml water over a pH range 1 to 7.5, and "highly permeable" when the extent of absorption in humans is determined to be 90% of an administered dose, based on mass balance or related to an intravenous reference dose. For a rapidly dissolving tablet, 85% of the labeled amount of drug substance must dissolve within 30 minutes. Thus, for rapidly dissolving solid oral dosage forms, the dose-to-solubility ratio (D:S) of the drug must be 250 ml over pH range of 1 to 7.5. Class I drug substances, which possess both high permeability through biological membranes and good solubility in water, have the preferred physicochemical properties. Most new chemical identities are water-insoluble lipophilic compounds or, in other words, Class II or Class IV compounds which are traditionally difficult to formulate into usable pharmaceutical products. (Cyclodextrin-based Drug Delivery, Loftsson, T., and O'Fee, R., 2002, Business Briefing: Pharmatech, pl36-140).